

UCSF COMMITTEE ON HUMAN RESEARCH  
EXPEDITED REVIEW APPLICATION  
12/17/2007

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**PART 1: ADMINISTRATIVE REQUIREMENTS**

<b>A. Principal Investigator:</b>			
Name and degree	University Title	Department	
Dean Schillinger, MD	Assoc. Clinical Professor	General Internal Medicine	
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<b>Co-Principal Investigator:</b>			
Name and degree	University Title	Department	
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<b>Additional Contact Person (if any):</b>			
Name	University Title	Department	
Campus Mailing Address (Box No.)	Phone Number	E-mail Address	
Send correspondence to (check <i>one</i> ): <input checked="" type="checkbox"/> [X] PI only <input type="checkbox"/> [ ] PI and Co-PI <input type="checkbox"/> [ ] PI and Additional Contact Person			
Study Title:		Application Type:	
<b>Harnessing Health IT for Self-Management Support and Medication Activation in a Medicaid Health Plan</b>		<input checked="" type="checkbox"/> [X] New Expedited Review Application <a href="#">Expedited Review Category:</a> <input type="checkbox"/> [ ] Response to "Contingent" or "Return" letter <input type="checkbox"/> [ ] Modification <input type="checkbox"/> [ ] Renewal Current CHR #: ____ Expiration date: ____	
<b>UCSF Sites (Check all that apply):</b>			
<input checked="" type="checkbox"/> [X] UCSF <input type="checkbox"/> [ ] Cancer Center <input checked="" type="checkbox"/> [X] SFGH <input type="checkbox"/> [ ] ITN <input type="checkbox"/> [ ] Fresno			
<b><u>CTSI CRC Sites (Check all that apply):</u></b>			
<input type="checkbox"/> [ ] Moffitt Inpatient Unit <input type="checkbox"/> [ ] SFGH Inpatient Unit <input type="checkbox"/> [ ] Moffitt Pediatric Inpatient Unit <input type="checkbox"/> [ ] Kaiser Oakland DOR <input type="checkbox"/> [ ] Moffitt Outpatient Unit <input type="checkbox"/> [ ] SFGH Outpatient Unit <input type="checkbox"/> [ ] Moffitt Pediatric Outpatient Unit <input type="checkbox"/> [ ] CHORI Pediatric <input type="checkbox"/> [ ] Mt. Zion Outpatient unit <input type="checkbox"/> [ ] VAMC Outpatient Unit <input type="checkbox"/> [ ] Pediatric Clinical Care Units <input type="checkbox"/> [ ] CHORI Adult			
<b><u>UCSF Affiliated Sites (Check all that apply):</u></b>			
<input type="checkbox"/> [ ] VAMC <input type="checkbox"/> [ ] Gladstone <input type="checkbox"/> [ ] Gallo <input checked="" type="checkbox"/> [X] SFDPH <input type="checkbox"/> [ ] IOA <input type="checkbox"/> [ ] BSRI <input type="checkbox"/> [ ] BCP			
<b>Non-UCSF Affiliated Sites - Attach <a href="#">IRB Approval Certification Supplement</a> for all items checked below:</b>			
<input type="checkbox"/> [ ] Other UC Campus (please identify): <input type="checkbox"/> [ ] Foreign Country <input type="checkbox"/> [ ] Other			

**B. Funding:** If this study is eligible for “Just in Time” NIH review, do not submit your application to the CHR until you have received notification from the federal granting agency that your study appears to be in a fundable range. If this study is federally funded please complete section B.6.

Check all that apply:

<b>1. Type of funding:</b> <input checked="" type="checkbox"/> Contract/Grant <input type="checkbox"/> Subcontract <input type="checkbox"/> Drug/device donation <input type="checkbox"/> Departmental <input type="checkbox"/> Gift <input type="checkbox"/> Student project <input type="checkbox"/> Other: ____  Have funds been awarded? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> Pending <input type="checkbox"/> No  Award No.: _ 1R18HS017261-01  <b>Proposal Express</b> number(s): ____	<b>2. Source of funding:</b> <input checked="" type="checkbox"/> Federal Government <input type="checkbox"/> Other Gov. (e.g., State, local) <input type="checkbox"/> Industry** <input type="checkbox"/> Other Private <input type="checkbox"/> Campus/UC-Wide program <input type="checkbox"/> Departmental Funds <input type="checkbox"/> Other:  <b>Specify name of source designated above: AHRQ</b> ____	<b>3. Funds will be awarded to/through:</b> Dept./ORU: <u>Institution</u> <u>Federal Wide Assurance (FWA) No.</u> <input checked="" type="checkbox"/> UCSF ..... 00000068 <input type="checkbox"/> Blood Centers of the Pacific ..... 00002111 <input type="checkbox"/> Blood Systems Research Institute ..... 00006454 <input type="checkbox"/> Gallo Institute ..... 00000304 <input type="checkbox"/> Gladstone Institute ..... 00000087 <input type="checkbox"/> Institute on Aging ..... 00002525 <input type="checkbox"/> JNCIRE ..... 00000256 <input type="checkbox"/> S.F. Dept. of Public Health ..... 00000162 <input type="checkbox"/> SFVAMC Research Office ..... 00000280
<b>4. UCSF (or affiliate) financial contact person for IRB review recharge:</b>	Margaret DiLaura, Box 1364	
<b>5. Grant Title and PI (if different from above):</b>		
<b>6. CHR Protocol/Federal Grant or Contract Comparison (New CHR Studies Only)</b> If this study is federally funded, please submit one copy of one of the following documents (unless there is more than one grant or contract involved; in that case, submit one copy for each associated grant or contract). Please indicate which document you have attached: <input type="checkbox"/> The Research Plan, including the Human Subjects, Section E of your NIH grant <input checked="" type="checkbox"/> For other federal proposals (contracts or grants), the section of the proposal describing human subjects work, or <input type="checkbox"/> The section of your progress report if it provides the most current information about your human subjects work.		
<b>7. If there are any significant discrepancies between this CHR application and the grant or contract or if this is a training grant please explain here:</b>  		
<b>8. Secondary sponsors:</b> If there are multiple sources of funding for this study, please describe the additional funding:  		

**C. Scientific Merit Review:** This study has received or will receive [scientific merit review](#) from (check all that apply):

☐ NIH    ☐ Cancer Center\*    ☐ CTSI CRC    ☐ SFVAMC    ☐ CHORI    ☐ Kaiser Oakland DOR    ☐ GESCR  
☐ Dept. Review                      ☐ Other: \_\_\_\_

\*Required prior to final CHR approval for oncology studies.

**D. Key Personnel:** All [key personnel](#) including the PI and Co-PI must be listed below along with a brief statement of their [qualifications](#) and study role(s). *If the SF VAMC is a study site*, please identify the principal VAMC investigator, unless already listed as PI or Co-PI above. For questions regarding the VAMC application process, please contact the VA Clinical Research Office at 221-4810 ext.4655. **Please note:** All Key Personnel at UCSF or UCSF affiliated sites must complete the online UCSF Human Subject Protections Training program (<https://www.researchonline.ucsf.edu/>).

Investigators and other personnel [and institution(s)]:	Qualifications:	Study role(s):
Dean Schillinger, MD Margaret Handley, PhD MPH Urmimala Sarkar, MD MPH	Associate Prof Of Medicine Adjunct Asst Prof Fam Comm Med Research Fellow, General medicine	Principal Investigator Epidemiologist/Investigator Research fellow/Investigator

**E. Statement of Financial Interest:** Does the PI or any investigator have any [financial interests](#) related to this clinical study?

☐ Yes ☒ No

If Yes, Attach [Disclosure Of Investigators' Financial Interests Supplement](#)

**F. Other Approvals/Regulated Materials:** Does this study require approval or authorization from any of the following regulatory committees, or involve the use of the regulated materials listed below? Follow the hyperlinks for more information. If "Yes," complete the applicable section(s) below.

☐ Yes ☒ No

☐ [Biological Safety Committee](#)

BUA #:

☐ [Human Stem Cells](#)

Attach - [Human Stem Cell Supplement](#)

**G. Principal Investigator's Certification:**

- I certify that the information provided in this application is complete and correct.
- I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project.
- I will comply with all policies and guidelines of UCSF and affiliated institutions where this study will be conducted, as well as with all applicable federal, state and local laws regarding the protection of human subjects in research.
- I will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the CHR-approved protocol.
- I will not modify this CHR-certified protocol or any attached materials without first obtaining CHR approval for an amendment to the previously approved protocol.
- I assure that the protected health information requested, if any, is the minimum necessary to meet the research objectives.
- I assure that the protected health information I obtain, if any, as part of this research will not be reused or disclosed to any parties other than those described in the CHR-approved protocol, except as required by law.
- I assure that adequate resources to protect participants (i.e., personnel, funding, time, equipment and space) are in place *before* implementing the research project, and that the research will *stop* if adequate resources become unavailable.

\_\_\_\_\_  
Principal Investigator's Signature

\_\_\_\_\_  
Date

## **PART 2: STUDY DESIGN**

Complete items A-E using clear, concise, non-technical, lay language (i.e., the type of language used in a newspaper article for the general public) wherever possible. Define all acronyms. Use caution when cutting and pasting from another application or protocol to ensure that information is complete, supplemented where necessary, is pasted in a logical order, and is relevant to the specific section.

Space limits are recommendations and should be adjusted as needed, but the total length for sections A-E should not exceed 5 pages.

For modifications and renewals, please highlight in *italics* all changes from previously approved version.

### **A. Synopsis**

We will be conducting an evaluation of a quality improvement initiative that the San Francisco Health Plan (SFHP), a large Medicaid managed care plan in SF, is conducting for approximately 500 SFHP enrollees with diabetes who are attending 4 Community Health Network Clinics in San Francisco (CHNSF) over a two year period. The intervention that SFHP is implementing is Automated Telephone Support Management (ATSM), a health IT innovation used as adjunct to care management. The partnership with UCSF-SFGH researchers is based on previous work we have done in the CHNSF regarding using ATSM among diabetes patients to improve self-management activities and other health outcomes, but **in the current demonstration project and evaluation, the recruitment of participants and implementation of the intervention will be done by the SFHP; UCSF will only conduct an evaluation.** The Governing Board at the SFHP decided to adopt the ATSM model for its growing number of diabetes patients, to dedicate nursing staff to respond to ATSM data and engage with enrollees and their providers, to underwrite the costs of ATSM implementation, to randomly assign their patients to one of two types of ATSM (one that involves medication review/intensification vs. one that only delivers behavioral support), and to contact eligible SFHP members for ATSM and also to briefly describe the evaluation study to be carried out by UCSF. We, as UCSF researchers, will evaluate the impact of the interventions on patient outcomes. There will be limited contact with patients by the UCSF research team. UCSF research staff will only contact patients after SFHP has determined that their patients are interested in being contacted about the evaluation; and there will be no collection of personal health information by UCSF evaluators. UCSF research staff will conduct a telephone survey after verbal consent procedures, at baseline and 9 months (and for patients wait-listed, again at 18 months), for patients participating in the ATSM intervention. The SFHP will maintain an ID link between patients who are in the intervention and who are conducted about the evaluation, but they will not have patient-linked survey data, nor will UCSF have linked health-related data from the SFHP regarding patient outcomes, **although de-identified data will be included in the UCSF evaluation.** UCSF will conduct the quantitative data analyses of de-identified data provided to us by the SFHP at set times over the study period to examine the impact of the interventions on clinical outcomes. The evaluation will focus on the effects of ATSM on both patient-centered outcomes and on clinical outcomes through this “real-world” effectiveness study. The fact that recruitment and implementation will be carried out by SFHP, that SFHP will maintain the link to patients in the evaluation but will not have the survey data linked to individuals, and that only SFHP will have control over the personal health information of patients, has important implications for generalizability.

**B. Hypothesis(es):**

The goal of the evaluation study is to determine if the ATSM model improves diabetes self-management and other health behaviors and will have improved clinical outcomes compared with patients who do not have ATSM exposure.

**C. Specific Aims:**

**Specific Aim.** To measure the effects of a Medicaid health plan-directed automated telephone self-management support system (ATSM) on patient outcomes among ethnically diverse health plan enrollees with diabetes.

**D. Background and Significance:**

ATSM is a health IT application that holds particular promise for more vulnerable populations (Piette and Schillinger, 2007). ATSM is a **phone** technology to provide surveillance and education and to prioritize further telephone care management efforts for those most in need. ATSM can be used to promote collaborative goal-setting in the form of behavioral ‘action plans’ wherein patients set, and hopefully achieve, short-term goals to improve their self-management (Lorig, 2006). Collaborative goal-setting and action planning represent a core element of self-management support (Fischer et al., 2005 and Glasgow et al., 2005). ATSM can also provide individualized assessment, skills enhancement, health education, follow-up and support, access to community resources and continuity of clinical care. Efficacy studies of ATSM have revealed improvements in satisfaction and functional status among patients with diabetes (Piette, Weinberger and McPhee, 2000 and Piette et al., 2000) for both English and Spanish speakers. As opposed to personal computer-based health IT applications, our group has shown particularly high levels of reach of ATSM for patients with limited literacy and limited English proficiency, and for those who have Medicaid or no insurance (Schillinger et al., 2007). We have found that exposure to the ATSM model yields robust improvements in patient-centered dimensions of chronic disease care quality, including interpersonal communication, assessment of chronic illness care, self-efficacy, and functional status. ATSM can also serve a surveillance function to identify previously undetected potential adverse events and actual adverse events occurring at home. However, in the absence of medication intensification, ATSM alone does not appear to be associated with improvements in other clinical endpoints. Prior studies that used proactive calling have engaged care managers to up-titrate medications, including insulin (Young et al., 2005 and Shojania et al., 2006), but these were efficacy trials and did not assess patient-centeredness. We believe that through the ATSM interventions implemented by the SFHP, including one ATSM arm that will focus on medication intensification, that additional improvements in patient outcomes will be achieved.

**E. Preliminary Studies:**

Our group has recently completed a randomized controlled trial of ATSM among English, Spanish, and Chinese speaking patients with poorly controlled diabetes cared for in the Community Health Network of San Francisco. The main goal of ATSM is to promote self-efficacy by assisting patients in developing and maintaining behavioral changes through patient-generated ‘action plans’. We demonstrated that engagement with ATSM was especially high among participants with communication barriers, such as limited literacy and limited English proficiency. Receipt of ATSM was associated with robust improvements in patient-centered dimensions of chronic disease care quality, including interpersonal communication, assessment of chronic illness care, self-efficacy, and functional status (Schillinger et al., 2007). In addition, we have shown that ATSM can provide a novel, real-time surveillance function for identifying previously undetected potential adverse events and actual adverse events occurring at home, often in the context of patients’ self-management of diabetes (Sarkar et al., 2007). Receipt of ATSM, however, was not associated with improvements in either blood pressure or glycemic control. We hypothesize that this lack of benefit with respect to metabolic control partially can be explained by the fact that medication intensification/activation was not an explicit goal of our patient-centered, health IT-facilitated ATSM model.

## F. Design

1. (Check all that apply):

☐ Randomized      ☐ Blinded      ☐ Investigational intervention without random assignment  
☒ Behavioral

☐ Multicenter: If so, is UCSF the coordinating center or the prime grant holder?

☐ Yes      ☐ No

If yes, please complete Section III of the [IRB Approval Certification Supplement](#)

2. Additional description of [general study design](#). Attach flow diagram if appropriate.

Space limit: half page

This study is an evaluation of a large ATSM/QI initiative at the San Francisco Health Plan (SFHP) involving approximately 500 patients with diabetes who speak English, Spanish, or Cantonese. SFHP will be enrolling patients into one of 3 programs: wait-list, ATSM only, and ATSM plus medication activation. We will enroll over the telephone a subset of exposed SF Health Plan members, without collecting PHI information from them, in order to examine the effects of ATSM on changes in patient-centered measures. We will analyze de-identified clinical data provided to us by the SFHP to measure effects on clinical outcomes, such as hemoglobin A1c and utilization. To ensure that UCSF does not have access to PHI and that SFHP does not know who is participating in the evaluation or have linked survey results to their patients, the following steps are in place:

1. The SFHP will create and maintain a unique SFHP- ATSM ID number separate from the patient's SFHP ID, but is instead created just for the ATSM program. For patients who agree to be contacted by UCSF, this SFHP-ATSM ID along with last name, language spoken and telephone number will be given verbally to UCSF research staff.

2. UCSF will create a unique UCSF identifier for all patients who are interviewed by UCSF for the evaluation.

3. At the end of the intervention, SFHP will provide UCSF with datasets that only use the unique SFHP-ATSM ID number, and UCSF will link these data with survey results for the evaluation.

4. UCSF will then provide the SFHP with survey data in aggregate only identified by the unique UCSF identifier. Through these steps there will be no exchange of data between the SFHP and UCSF that is identifiable.

## G. **Statistical Analysis:**

Several statistical analyses will be done including: Calculation of descriptive statistics such as mean, median, SD, range, tallies; estimation of differences between intervention groups with comparison by t-test or Mann-Whitney test, and regression techniques such as logistic regression, or Cox proportional hazards regression.

## H. **Sample Size:** Indicate how many subjects will be studied and why this number was chosen.

We anticipate that close to 500 patients will be enrolled in the ATSM interventions by SFHP, and be included in the de-identified data sets for analysis. We anticipate that close to 400 patients will agree to be interviewed on the telephone at baseline and follow up by the UCSF evaluation team.

## **PART 3: PROCEDURES**

A. Check all that apply.

☐ [Human Biological Specimen Banking](#) Attach - [Banking Supplement](#)  
☐ [Genetic Testing](#)

**B.** Please list, in sequence, all study procedures, tests, and treatments required for the study. Indicate which would be done even if a subject does not enroll in the study. Include a detailed explanation of any experimental procedures. Attach table if available.

1. After the SFHP has determined which patients are eligible for the ATSM interventions, they will contact eligible patients by telephone using a scripted interview in the patient's preferred language (Attachment 1). During the phone call, patients will be allowed to opt out of the ATSM intervention, the UCSF evaluation, or both the ATSM intervention and the evaluation. UCSF staff will only contact patients who agree to both the ATSM intervention and to be contacted about the evaluation.
2. SFHP staff, after enrolling a patient in the ATSM program and who also agreed to be contacted by the UCSF evaluation team, will page the UCSF evaluation team to give UCSF researchers the last name, language and phone number of the patient and the unique SFHP- ATSM identifier for the patient. UCSF research staff will then have a research assistant call the patient in the appropriate language and ask about participation in the UCSF evaluation using a verbal consent process (Attachment 2). In our previous work, we used a pager to alert research staff who spoke the matching language of the patient, to enroll them at the time that the patient's eligibility was first determined, and we believe that this approach is essential to the success of a 3 languages project, and feasible only with a telephone consent, since the patients will be contacted by telephone at their homes by the SFHP about the intervention.
3. If patients agree to the verbal consent (Attachment 2), they will be interviewed on the telephone using a close-ended survey adapted from our previous studies (Attachment 3).

**C.** How much time will be required of the subjects, per visit and in total for the study?

Each telephone interview will last approximately 20 minutes and will be conducted at baseline and 9 months later. Subjects who have been wait-listed by SFHP will be interviewed again at 18 months.

**D.** Will any interviews, questionnaires, surveys or focus groups be conducted for the study? If "Yes," please name any standard instruments used for this study and attach any non-standard instruments.

☒ Yes   ☐ No

see ATSM Survey (Attachment 3)

**E.** Will any procedures or tests be done off-site by non-UCSF personnel? If "Yes," please explain.

☐ Yes   ☒ No

## **PART 4: ALTERNATIVES**

**A.** Describe the [alternatives to study participation](#) that are available to prospective subjects.

Patients can opt out of the UCSF evaluation and still receive the ATSM intervention.

**B.** Is study drug or treatment available off-study? If "Yes," discuss this in the consent form.

☐ Yes   ☒ No   ☐ N/A

## **PART 5: RISKS AND BENEFITS**

**A.** [Risks and Discomforts](#):

**1.** Describe the risks and discomforts of any study procedures.

Patients in the evaluation may experience discomfort associated with discussing their chronic health condition. For the analysis of the health outcomes and effectiveness of the intervention, we have developed a strategy to use only de-

**A. Risks and Discomforts:**

**1. Describe the risks and discomforts of any study procedures.**

identified datasets for this, minimizing potential losses of privacy.

**2. Describe the steps you have taken to minimize the risks/discomforts to subjects:**

We have used mostly closed ended questions and have provided allowance for patients to opt out or skip any questions they do not wish to answer. We will use de-identified datasets and unique identifiers for the survey data to determine the study evaluation outcomes.

**B. Confidentiality and Privacy:** Privacy concerns people, whereas confidentiality concerns data. Specifically, confidentiality refers to the researcher's agreement with the participant about how the participant's identifiable private information will be handled, managed and disseminated. While privacy refers to a person's desire to control the access of others to themselves. **Address each of the following privacy issues in questions 1-3 below:**

**1. How will the investigator access information from or about participants?**

We will use a unique identifier for each patient we interview. We will also have de-identified data that is linked to a unique SFHP ATSM identifier that we can link to the interview data.

**2. How will the investigator maintain privacy in the research setting(s),**

We will maintain the following privacy protections: de-identified data, only last name, language and telephone number, unique UCSF and SFHP identifiers. All research will be stored in locked cabinets in the Division of General Medicine at SFGH, Bldg 10 3<sup>rd</sup> floor; electronic data will be pass-word protected.

**3. What are the consequences to participants of a loss of privacy (e.g., risks to reputation, insurability, other social risks):**

Patients may feel some discomfort about their responses to survey items.

**The following questions address confidentiality issues:**

**4. Identifiers:** Please indicate all identifiers that may be included in the research records for the study. Check all that apply.

<input checked="" type="checkbox"/> Names	<input type="checkbox"/> Social Security Numbers*	<input type="checkbox"/> Device identifiers/Serial numbers
<input type="checkbox"/> Dates	<input type="checkbox"/> Medical record numbers	<input type="checkbox"/> Web URLs
<input type="checkbox"/> Postal address	<input type="checkbox"/> Health plan numbers	<input type="checkbox"/> IP address numbers
<input checked="" type="checkbox"/> Phone numbers	<input type="checkbox"/> Account numbers	<input type="checkbox"/> <a href="#">Biometric identifiers</a>
<input type="checkbox"/> Fax numbers	<input type="checkbox"/> License/Certificate numbers	<input type="checkbox"/> Photos and comparable images
<input type="checkbox"/> Email address	<input type="checkbox"/> Vehicle id numbers	<input type="checkbox"/> [*] Any other unique identifier
<input type="checkbox"/> None of the 18 identifiers listed above		*Required for studies conducted at the VA

\* primary language

**5. Determining Whether HIPAA Regulations Apply to This Study:** Please answer the questions below for the items identified in the above section. Check all that apply:

Is any of the study data:

- ☐ Derived from a medical record? *Please identify source:*  
☐ Added to the hospital or clinical medical record?  
☐ Created or collected as part of health care?  
☐ Used to make health care decisions?

**HIPAA regulations apply.**

The information identified in section B.4. above is PHI.

- ☒ Obtained from the subject, including interviews, questionnaires?  
☐ Obtained from a foreign country or countries only?  
☐ Obtained from records open to the public?  
☐ Obtained from existing research records?  
☐ None of the above.

**HIPAA regulations do not apply.**

The information identified in section B.4. above is not PHI.

**If HIPAA regulations apply**, you are required to obtain individual [subject authorization](#) or a [CHR-approved waiver of authorization](#), or both, to be allowed access to medical records. For the VA, use the [SFVAMC authorization](#). (The one exception to these requirements is the use of a [Limited Data Set](#) along with a [Data Use Agreement](#).)

**6. Use and Disclosure of Personal Health Information:** Please indicate to whom or where you may disclose any of the identifiers listed above as part of the study process. Check all that apply:

**B. Confidentiality and Privacy:** Privacy concerns people, whereas confidentiality concerns data. Specifically, confidentiality refers to the researcher's agreement with the participant about how the participant's identifiable private information will be handled, managed and disseminated. While privacy refers to a person's desire to control the access of others to themselves. **Address each of the following privacy issues in questions 1-3 below:**

- ☒ We do not plan to share any of the personally identifying information listed above outside the research team.  
☐ The subject's medical record  
☐ The study sponsor: *please indicate:*  
☐ The US Food & Drug Administration (FDA)  
☐ Others: *please indicate:*  
☐ A Foreign Country or Countries

**7. Data Security:** Identifiable data should not be stored on laptops, PDA's or other portable devices. Please indicate how study data are kept secure. Check all that apply:

- ☐ Data are coded; data key is destroyed at end of study or *provide date:*  
☒ Data are coded; data key is kept separately and securely  
☒ Data are kept in locked file cabinet ☒ Electronic data are protected with a password  
☒ Data are kept in locked office or suite ☒ Data are stored on a secure network

**8.** Describe any additional steps taken to assure that identities of subjects and any of their health information which is protected under the law is kept confidential. If video or audio tapes will be made as part of the study, [disposition of these tapes](#) should be addressed.

This study is an evaluation of a large ATSM/QI initiative at the San Francisco Health Plan (SFHP) involving approximately 500 patients with diabetes. We will enroll over the telephone a subset of exposed health plan enrollees, without collecting PHI information from them, in order to examine the effects of ATSM on changes in patient-centered measures. To ensure that UCSF does not have access to PHI and that SFHP does not know who is participating in the evaluation or have linked survey results to their patients, the following steps are in place:

1. The SFHP will create and maintain a unique SFHP- ATSM ID number that is not related to the patient's SFHP id, but is instead created just for the ATSM intervention. For patients who agree to be contacted by UCSF, this SFHP id along with last name and telephone number will be given verbally to UCSF research staff.
2. UCSF will create a unique UCSF identifier for all patients who are interviewed by UCSF for the evaluation.
3. At the end of the intervention, SFHP will provide UCSF with datasets that only use the unique SFHP- ATSM ID number, and UCSF will link these data with survey results for the evaluation.
4. UCSF will then provide the SFHP with survey data in aggregate only identified by the unique UCSF identifier. Through these steps there will be no exchange of data between the SFHP and UCSF that is identifiable.

**9. Reportable Information:** Is it reasonably foreseeable that the study will collect information that State or Federal law requires to be reported to other officials (e.g., child or elder abuse) or ethically requires action (e.g., suicidal ideation)? If "Yes," please explain below and include a discussion of the reporting requirements in the consent form.

☐ Yes ☒ No

**C. Benefits:**

**1.** Are there potential direct benefits to study subjects? If "Yes," please describe below.

☒ Yes ☐ No

Most expected benefits are related to the intervention beyond the scope of UCSF responsibilities; the UCSF evaluation benefits are in helping determine if the intervention is effective for SFHP patients with diabetes.

**2.** What are the potential benefits to society?

<b>C. <u>Benefits:</u></b> 1. Are there potential direct benefits to study subjects? If “Yes,” please describe below.	[X ]Yes    [ ]No
Determining which aspects of the ATSM are most effective for improving diabetes care and outcomes, particularly for patients who are in poor glycemic control and who do not speak English.	

<b>D. Risk/Benefit Analysis:</b> How do the benefits of the study outweigh the risks to subjects?
The research evaluation has very few risks and only indirect benefits for other patients with diabetes. Participants will receive \$50 reimbursements/incentives for responding to each questionnaire.

## **PART 6: SUBJECT INFORMATION**

<b>A. Number of Subjects:</b> 1. How many subjects will be enrolled at UCSF and affiliated institutions?	300-350
2. How many subjects will be enrolled at all sites (i.e., if multicenter study)?	300-350
3. How many people do you estimate you will need to consent and screen here (but not necessarily enroll) to get the needed subjects?	350-400

<b>B. Types of Subjects:</b> Check all that apply. Click on links for additional instructions.	
<input type="checkbox"/>	<a href="#">Minors Attach - Inclusion of Minors Supplement</a>
<input type="checkbox"/>	<a href="#">Subjects unable to consent Attach - Surrogate Consent or Emergency Waiver of Consent Supplement</a>
<input type="checkbox"/>	<a href="#">Subjects with Diminished Capacity to Consent</a>
<input checked="" type="checkbox"/>	<a href="#">Subjects Unable to Read, Speak, or Understand English</a> – Complete Part 8.D of this application
<input type="checkbox"/>	<a href="#">Pregnant Women</a> – Complete Part 6.G of this application
<input type="checkbox"/>	<a href="#">Fetuses</a>
<input type="checkbox"/>	<a href="#">Neonates</a>
<input type="checkbox"/>	<a href="#">Prisoners Attach - Inclusion of Prisoners Supplement</a>
<input type="checkbox"/>	Inpatients
<input checked="" type="checkbox"/>	Outpatients
<input type="checkbox"/>	Healthy Volunteers
<input type="checkbox"/>	Staff of UCSF/affiliated institution

<b>C. Eligibility Criteria:</b> 1. General description of subject population(s):
To be eligible for the ATSM Program, SFHP members will be identified who meet the following criteria: diabetes diagnosis, who attend 4 CHNSF clinics, are ages 18 or above, speak English, Spanish or Cantonese, have a touch tone phone, have had one or more clinic visits in the preceding 12 months and will be in the SF Bay Area for the following six months, and are not pregnant. All such subjects will eligible for UCSF interviews if they have accepted the invitation to do so from SFHP.
2. <a href="#">Inclusion Criteria:</a>
Patients in the ATSM Evaluation Study must be able to provide verbal consent.
3. <a href="#">Exclusion Criteria:</a>
Patients unable to provide verbal consent.

<b>D.</b> How (chart review, additional tests/exams for study purposes), when and by whom will eligibility be determined?
We will not determine eligibility for the ATSM evaluation study beyond what the SFHP has determined for the ATSM intervention, except that UCSF will only enroll patients who are able to provide verbal consent. We will determine eligibility for verbal consent on the telephone.

<b>E.</b> Are there any inclusion or exclusion criteria based on <i>gender, race</i> or <i>ethnicity</i> ? If “Yes,” please explain the nature and rationale for the restrictions below.	[ ]Yes    [X ]No
--	------------------

E. Are there any inclusion or exclusion criteria based on <i>gender, race</i> or <i>ethnicity</i> ? If “Yes,” please explain the nature and rationale for the restrictions below.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

<b>F. Populations Likely to be Vulnerable to Coercion or Undue Influence:</b>
1. List subject groups who are likely to be vulnerable to coercion or undue influence, such as mentally disabled persons, economically or educationally disadvantaged persons, or investigators’ staff or students. <b>Omit minors, those unable to consent for themselves, and prisoners</b> (who are covered by separate Supplements); <b>for pregnant women, fetuses, and neonates, see section G below</b> ):
Some participants may have limited educational attainment.
2. Explain why it is appropriate to include the groups listed above in this particular study:
Approximately half of Medicaid/Medi-cal members have less than a high school education. It is critical that we include such members so as to increase generalizability as well as explore whether ATSM disproportionately benefits those with lower educational attainment.
3. Describe additional safeguards that have been included in the study to protect the rights and welfare of these subjects and minimize coercion or undue influence. For example, you might provide competence evaluations (specify) for the mentally disabled, payment amounts calibrated to be non-coercive for the financially disadvantaged, extra-careful evaluations of subjects’ understanding of the study, advocates to be involved in the consent process, or use flyers to recruit subjects instead of directly approaching staff or students:
We will ask the subjects to repeat back to us what it is they are consenting to and we will determine if they are able to understand the project well enough to consent. We anticipate that since the ATSM Evaluation Study will involve an interview right then on the phone, that this will not be hard to explain. After explaining the goals of the evaluation on the telephone, subjects that cannot explain in their own words the purpose of the study will be deemed unable to provide consent, and will not be enrolled. The same process will take place for Spanish and Cantonese speaking individuals to ensure comprehension among all languages.

<b>G. Pregnant Women, Human Fetuses, and Neonates:</b>
Identify all sections of 45 CFR 46 Subpart B (see <a href="#">Chart</a> ) under which you believe the research falls and provide study-specific information showing why the research falls within those sections:

## **PART 7: RECRUITMENT**

A. Please review <a href="#">CHR Recruitment Guidelines</a> for more information about acceptable recruitment methods. Note that all advertisements, whether posted or broadcast, and all correspondence used for purposes of recruitment require CHR review and approval before they are used. Check all that apply:	
<input type="checkbox"/>	Study investigators recruit their own patients directly and/or nurses or staff working with researchers approach patients. <b>Please explain in Section B.</b>
<input type="checkbox"/>	Study investigators send a CHR-approved letter to colleagues asking for referrals of eligible patients interested in the study. The investigators may provide the referring physicians a CHR-approved Information Sheet about the study to give to the patients. If interested, the patient will contact the PI. Or, with documented permission from the patient, the PI may be allowed to talk directly with patients about enrollment. <b>Attach letter for review.</b>
<input type="checkbox"/>	Study investigators provide their colleagues with a “ <a href="#">Dear Patient</a> ” letter describing the study. This letter can be signed by the treating physicians and would inform the patients how to contact the study investigators. The study investigators may not have access to patient names and addresses for mailing. <b>Attach letter for review.</b>
<input type="checkbox"/>	Advertisements, notices, and/or media used to recruit subjects. The CHR must first approve the text of these, and interested subjects will initiate contact with study investigators. <b>Attach ads, notices, or media text for review. In Section B, please explain where ads will be posted.</b>
<input checked="" type="checkbox"/>	Study investigators request a <a href="#">Waiver of Consent/Authorization</a> for recruitment purposes. This waiver is an exception to the policy but may be requested in circumstances such as:

A. Please review <a href="#">CHR Recruitment Guidelines</a> for more information about acceptable recruitment methods. Note that all advertisements, whether posted or broadcast, and all correspondence used for purposes of recruitment require CHR review and approval before they are used. Check all that apply:	
<input type="checkbox"/>	Minimal risk studies in which subjects will not be contacted (i.e., chart review only);
<input type="checkbox"/>	Review of charts is needed to identify prospective subjects who will then be contacted. (Explain in <a href="#">Waiver form</a> );
<input checked="" type="checkbox"/>	Large-scale epidemiological studies and/or other population-based studies when subjects may be contacted by someone other than personal physician. (Explain in <a href="#">Waiver form</a> .)
<input type="checkbox"/>	Direct contact of potential subjects who have previously given consent to be contacted for participation in research. Clinic or program develops a CHR-approved recruitment protocol that asks patients if they agree to be contacted for research (a recruitment database) or consent for future contact was documented using the consent form for another CHR-approved study. <b>Please explain in Section B.</b>
<input type="checkbox"/>	Study investigators list the study on the <a href="#">UCSF Clinical Trials Seeking Volunteers</a> web page or a similarly managed web site. Interested subjects initiate contact with investigators.
<input type="checkbox"/>	Study investigators recruit potential subjects who are unknown to them. Examples include snowball sampling, use of social networks, direct approach in public situations, random digit dialing. <b>Please explain in Section B.</b>

B. Provide detail in the space below ( <i>i.e., how, when, where and by whom are potential subjects approached?</i> ).
Potential subjects will first be enrolled in the ATSM program by SFHP staff. These SFHP staff will inquire as to the patient's interest in the ATSM Evaluation Study using the script provided in Attachment 1. Patients who agree to be contacted by UCSF research staff will have their phone number, language and last name given directly to UCSF staff after the ATSM Program enrollment is completed. SFHP staff will page UCSF research associates who will then call and describe the ATSM Evaluation Study to the patient.

## **PART 8: INFORMED CONSENT PROCESS**

A. Check all that apply:	
<input type="checkbox"/>	Signed consent will be obtained from subjects and/or parents (if subjects are minors),
<input checked="" type="checkbox"/>	<a href="#">Verbal consent</a> will be obtained from subjects, using an:
<input type="checkbox"/>	Information sheet (attach)
<input checked="" type="checkbox"/>	Script (attach)
<input type="checkbox"/>	Signed consent will be obtained from <a href="#">surrogates</a> <b>Attach - <a href="#">Surrogate Consent Supplement</a></b>
<input type="checkbox"/>	<a href="#">Informed consent will not be obtained</a> . <b>Attach - either the <a href="#">Waiver of Consent/Authorization</a> or the <a href="#">Emergency Waiver of Consent Supplement</a> as appropriate.</b>

B. In the space below, describe <i>how, where, when</i> and <i>by whom</i> informed consent will be obtained. How much time will prospective subjects be given to consider study participation? If special subject populations will be included, be sure to describe any <a href="#">additional plans for obtaining consent from particular populations</a> . Justify any plans to use verbal consent instead of signed consent.
<ol style="list-style-type: none"> <li>After the SFHP has determined which patients are eligible for the ATSM interventions, they will contact eligible patients by telephone using a scripted interview in the patient's preferred language (Attachment 1). During the phone call, patients will be allowed to opt out of the ATSM intervention, the UCSF evaluation, or both the ATSM intervention and the evaluation. UCSF staff will only contact patients who agree to both the ATSM intervention and to be contacted about the evaluation.</li> <li>SFHP staff who have finished enrolling patients in the ATSM intervention who have agreed to be contacted by the UCSF evaluation team, will page the UCSF evaluation team as soon as they finish enrolling the patient to give UCSF researchers the last name, language and phone number of the patient and the unique SFHP- ATSM identifier for the patient. UCSF research staff will then have a research assistant call the patient in the appropriate language and ask about participation in the UCSF evaluation. In our previous work, we used a pager to alert research staff who spoke the matching language of the patient, to enroll them at the time that the patient's eligibility was first determined, and we believe that this approach is essential to the success of a 3 languages project, and feasible with a telephone consent, since the patients will be contacted by telephone at their homes by</li> </ol>

**B.** In the space below, describe *how, where, when* and *by whom* informed consent will be obtained. How much time will prospective subjects be given to consider study participation? If special subject populations will be included, be sure to describe any [additional plans for obtaining consent from particular populations](#). Justify any plans to use verbal consent instead of signed consent.

the SFHP about the intervention.

- 3 Patients will be contacted by UCSF research team staff if they agree to the verbal consent (Attachment 2).
- 4 Patients will be interviewed on the telephone using a close-ended survey developed in our previous studies (Attachment 3).
- 5 Patients will be contacted by SFHP staff the following day after initial contact and will have up to a week to decide if they would like to partake in the study.

**C.** How will you make sure subjects understand the information provided to them?

We will ask them to repeat back to us what it is they are consenting to and we will determine if they are able to understand the project well enough to consent. We anticipate that since the ATSM Evaluation Study will involve an interview right then on the phone, that this will not be hard to explain. After explaining the goals of the evaluation on the telephone, subjects that cannot explain in their own words the purpose of the study will be deemed unable to provide consent, and will not be enrolled.

**D. Subjects Who Do Not Read, Speak, or Understand English.**

1. If you will enroll subjects who are unable to Read, Speak or Understand English, what method will you use to obtain consent? *Preferred Method* should be used if a substantial number of prospective subjects are expected to be non-English speakers. See [Those Who Do Not Read, Speak or Understand English](#) for details of methods.

[X] *Preferred Method*—Consent form and other study documents will be available in the subject's primary language. Personnel able to discuss participation in the patient's language will be present for the consent process.

[ ] *Short-Form*—A qualified interpreter will translate the consent form verbally, and subjects will be given the Experimental Subject's Bill of Rights in their primary language, following instructions in [Those Who Do Not Read, Speak or Understand English](#) for required witnessing and signatures.

2. How will you maintain the ability to communicate with non-English speakers throughout their participation in the study?

We have Spanish-English bilingual staff and Cantonese-English bilingual staff.

## **PART 9: FINANCIAL CONSIDERATIONS**

**A. Payments to Subjects:**

1. Will subjects receive payments or gifts for study participation? If "Yes," please review [CHR Subject Payment Guidelines](#) and complete the following:

[X]Yes [ ]No

2. Payments will be (check all that apply):

[ ] Cash [ ] Check [X] Other (describe below)

3. Please describe the schedule and amounts of payments, including the total subjects can receive for completing the study. If deviating from recommendations in Subject Payment Guidelines, include specific justification below.

For baseline and follow-up questioners patients will receive a reimbursement for the amount of fifty dollars.

**B. Costs to Subjects:** Will subjects or their insurance be charged for any study procedures? If "Yes," describe those costs below and explain why it is appropriate to charge those costs to the subjects.

[ ]Yes [X]No

ATSM will be a covered SFHP benefit

**C. Treatment and Compensation for Injury:** The investigators are familiar with and will follow the University of California policy and (if applicable) Veteran's Affairs policy regarding treatment and compensation for injury. If subjects are injured as a result of being in this study, treatment will be available. The costs of such treatment may be covered by the University of California, by the Department of Veteran's Affairs (for subjects eligible for veteran's benefits, if the SF VAMC is a study site), or by the study sponsor, if any, [depending on a number of factors](#). The University does not normally provide any other form of compensation for injury.

## **PART 10: BIBLIOGRAPHY**

1. SCHILLINGER, D., et al. Seeing in 3-D: examining the reach of diabetes self-management support strategies in a public healthcare system. Health Education and Behavior, 2007. In Press.
2. Piette, J. and Schillinger, D. Applying Interactive Health Technologies for Vulnerable Populations, in Caring for Vulnerable Populations: Principles, Practice and Populations, T. King, et al., Editors. 2007, Lange/McGraw-Hill.
3. Lorig, K. Action planning: a call to action. J Am Board Fam Med, 2006. 19(3): p. 324-5.
4. Fisher, E.B., et al. Ecological approaches to self-management: the case of diabetes. Am J Public Health, 2005. 95(9): p. 1523-35.
5. Glasgow, R.E., et al. Randomized effectiveness trial of a computer-assisted intervention to improve diabetes care. Diabetes Care, 2005. 28(1): p. 33-9.
6. Piette, J.D., Weinberger, M. and McPhee, S.J. The effect of automated calls with telephone nurse follow-up on patient-centered outcomes of diabetes care: a randomized, controlled trial. Med Care, 2000. 38(2): p. 218-30.
7. Piette, J.D., et al. Do automated calls with nurse follow-up improve self-care and glycemic control among vulnerable patients with diabetes? American Journal of Medicine, 2000. 108(1): p. 20-7.
8. Young, R.J., et al. Pro-active call center treatment support (PACCTS) to improve glucose control in type 2 diabetes: a randomized controlled trial. Diabetes Care, 2005. 28(2): p. 278-82.
9. Shojania, K.G. et al. Effects of quality improvement strategies for type 2 diabetes on glycemic control: a meta-regression analysis. JAMA, 2006. 296(4): p. 427-40.
10. Sarkar, U., Handley, M., Gupta, R., Tang, A., Murphy, E., Seligman, H., Shojania, K.G., Schillinger, D. Use of an Interactive, Health-IT Facilitated Self-Management Support Program to Capture Threats to Patient Safety Among Ambulatory Chronic Disease Patients. In press. JGIM. 2007.

## **PART 11: ATTACHMENTS**

Please list <a href="#">Attachments, Supplements and Appendices</a>	Version number(s) or date(s)
<ol style="list-style-type: none"> <li>1. Script from SFHP about the intervention and evaluation</li> <li>2. Verbal Consent script</li> <li>3. Evaluation Survey Instrument</li> <li>4. Text from the Original AHRQ Grant regarding data and privacy protections and safeguards.</li> <li>5. Waiver Form</li> </ol>	

**Attachment 1:**  
**Script from SFHP about the intervention and evaluation**

**Note: This is the script for the UCSF Research Associate for participation in the evaluation.**

Improving Diabetes Success for Patients in the SFHP

Telephone Patient Survey

Phone Number Called: \_\_\_\_\_  
Language: \_\_\_\_\_  
Subject's Birth Year: \_\_\_\_\_  
Subject's Sex: \_\_\_\_\_  
Subject's ID: \_\_\_\_\_  
Interviewer ID: \_\_\_\_\_  
Date and Time: \_\_\_\_\_

INTRODUCTION

HELLO

May I speak with <<INSERT PATIENT NAME>>?

1. [YES] (CONTINUE TO INTRO1)
2. [CALLBACK AT ANOTHER TIME] (SKIP TO VERIFY2)
3. [OFFERS OTHER NUMBER TO CALL] (SKIP TO VERIFY3)
4. [NO/REFUSAL] (SKIP TO CLOSE1)

Good morning/afternoon/evening, my name is <<INSERT INTERVIEWER NAME>>. I am calling from <<UC San Francisco>> about the new San Francisco Health Plan's Telephone Diabetes Project you are starting. We are conducting a survey of patients before they join the program so that we can look at what can help make it work better. We are collaborating with the San Francisco Health Plan by conducting independent interviews with hundreds of patients like you to understand more about how your diabetes affects you and your health care.

## INTRO1

We are doing this survey to find out how patients feel about their diabetes and about the care they are getting for their diabetes at <<SAN FRANCISCO HEALTH PLAN >>. If you agree to participate in this survey, we will ask you questions about your health care and your diabetes. I will read the questions to you. It will take about 20 minutes to answer all the questions. This survey will be conducted now and again in 9 months and possibly again in 18 months. You will receive \$50 each time that you participate in the survey.

You can decide not to be part of this survey by saying you do not want to answer any questions at all. You can also stop answering questions at any time while I am talking with you. The answers to your questions will not be given to the health plan or to your doctor. We will summarize them along with many other peoples' answers. We will not ask you for any information that could be used to figure out who you are. Your doctors, nurse practitioner, or other health providers will not be able to link you with your answers. You can be assured that taking part in this survey will not affect your legal rights or your healthcare at << SAN FRANCISCO HEALTH PLAN >>.

Your name and phone number will not show up anywhere with your answers which will be identified only by a study number. Researchers may link your answers to other information that the San Francisco Health Plan may have for patients, such as age and lab test results, like blood sugar values, but no names are included with this information. Information from this study could be published in medical journals or other health care publications; however, any information gained will be published as a summary of all the answers collected from all the patients who participate in this survey.

This survey will not be difficult for you. A few questions may make you feel uncomfortable. You may skip any questions that you do not want to answer. However, your answers are very important, and may help make care better for you and other people with diabetes in your community.

## CONSENT 1

- Do you understand all of the information I've read to you so far?
- Do you agree to take part in this survey?

READ TO ALL: If you have any questions about the study, you can call Drs. Dean Schillinger or Margaret Handley at 415-206-3696 to talk about the study.

PROCEED ONLY IF SUBJECT ANSWERS "YES" TO BOTH QUESTIONS – Document Date and Phone number called

DO NOT READ, FOR INTERVIEWERS ONLY:

VERBAL CONSENT GIVEN:

1. Yes—record date and phone number below
2. No (IF NO, STOP SURVEY and PROCEED TO CLOSE1)

If Yes: \_\_\_\_\_  
Date  
\_\_\_\_\_  
Phone Number Dialed

## VERIFY1

I'm sorry; I must have dialed or been given the wrong number. Is this <<INSERT PHONE NUMBER DIALED>>?

1. If Yes: I'm sorry, I was given a wrong number. Thank you for your time. Goodbye. (END)
2. If No: Thank you. (DIAL CORRECT NUMBER AND BEGIN AGAIN)

#### VERIFY2

We'll call back at another time. Can you say when might be a better time for us to call back? (RECORD PREFERRED TIME TO CALL BACK).

Thank you. We'll call back at <<INSERT TIME AND DATE OF PREFERRED TIME>>. Goodbye. (END)

#### VERIFY3

Thank you. We'll try to reach him/her at <<INSERT OTHER PHONE NUMBER PROVIDED>>. Goodbye. (END)

#### CLOSE1

Thank you very much for your time. Goodbye. (DESCRIBE NATURE OF REFUSAL OR TERMINATION BELOW AND END)

---

### **Attachment 2:** **Verbal Consent Script**

The San Francisco Health Plan Enrollment Outreach Call: English, Spanish, and Cantonese

Note: This call will come from SFHP not UCSF investigators.

Hello, I am calling from the San Francisco Health Plan; can I please speak with (Mr. or Ms. Formal Last Name)?

Eligibility Qs: Do you have diabetes? Is (language) your most comfortable language to speak? If not (language), which language is?

We are calling about a new program for diabetes that has been found to help people feel better. Your doctors know about this program and agree that it might help you. It is a covered benefit and is free to you. Would you like to hear about the program?

If YES, proceed with: The program allows you to give us information about your diabetes that we can check over with a nurse who speaks the same language as you. She can help you manage your diabetes and answer questions. The way it works is that we will call you once a week for 6 months to ask you a few questions at a time you choose. You answer by pressing the keys on your telephone. This part is automated and takes just a few minutes, maybe 5 or 10 minutes. Depending on your answers, you can choose to listen to recorded ideas that may help you with your diabetes, or you can just answer the questions, which are things like: "how many times did you check your blood sugar this week" or "do have you any questions that you would like a nurse to call you back about?" If you want a nurse to call you back no matter what you answer, you can push a key for that too. When you talk to her, she can help problem solve, make appointments, and do other things that are related to your health care or medications. If you are away for awhile or miss a call, you can call into the system for free. It is Ok to sometimes miss calls. Would you like to join this program? It is a free benefit under San Francisco Health Plan.

IF NO >> Thank you for your time. Would you mind telling me why you are not interested?

IF YES >>> What is the best time and day to receive the weekly calls? In what language?

What is the best telephone number for you? Do you plan to be out of the area over the next 6 months?

IF YES >>> continue to ask about UCSF Evaluation

We also want to ask if it is Ok for someone studying how well this program works to call you and interview you?

They are doctors and researchers who have done this same type of program here in San Francisco, at the University

of California San Francisco, and have found that it helps many diabetes patients feel better. They want to help us with this program. They would reimburse you for your time.

## FAQ's

Q: Why did you call me? I do not have diabetes

A: We're sorry. The information we received must have been wrong. We will correct it. Thank you.

Q: Do I have to pay anything to be in this program?

A: No, this is a covered benefit and is free to San Francisco Health Plan members who have diabetes.

Q: If I am not at home for a few weeks, would that be okay?

A: Yes, it is; we can have a nurse call you when you return.

Q: Does my doctor know about this program?

A: Yes, your doctor knows about the program and we will tell your doctor if you participate.

Q: Before you begin with the program would you like to talk with a SFHP nurse?

A: If yes, a San Francisco Health Plan Nurse will contact you over the next several days.

If no, call ends.

## **Attachment 3:**

### **Evaluation Survey Instrument**

[Copy from Eligibility Form]

**Group Assignment:**

**Study ID #:**

Language the patient is most comfortable speaking:

- ☐ 1 ENGLISH
- ☐ 2 CANTONESE
- ☐ 3 SPANISH
- ☐ 4 OTHER \_\_\_\_\_

### **Section 1: DEMOGRAPHICS**

[Don't read item unless you are unsure of patient's sex]

1. Are you male or female?

- ☐ 0 FEMALE
- ☐ 1 MALE

To begin, I'd like some basic information about you.

2. How old are you? \_\_\_\_\_ YEARS

3. How many years have you had diabetes? \_\_\_\_\_ YEARS

[If <1 yr, use decimal, e.g. 6 mos = 0.5 yr.  
Otherwise round to the nearest integer]

4. Where were you born? \_\_\_\_\_

[Don't read item]

4(a). Is place of birth in the U.S.?

- ☐ 1 YES
- ☐ 0 NO

5. In total, how many years have you lived in the U.S.? \_\_\_\_\_ YEARS

SCI

6. Are you currently married or in a long-term relationship?

- \_1 YES
- \_0 NO

7. How often do you visit friends and relatives?

- \_1 NEVER
- \_2 ONCE A YEAR OR LESS
- \_3 A COUPLE OF TIMES A YEAR
- \_4 1-3 TIMES A MONTH
- \_5 ONCE A WEEK
- \_6 SEVERAL TIMES A WEEK

8. On average, how many different homes of friends or relatives do you visit per month?

- \_1 NONE
- \_2 1 TO 2
- \_3 3 TO 4
- \_4 5 to 6
- \_5 7 to 10
- \_6 More than 10

9. How many people usually come to see you or call you per day?

- \_1 NONE
- \_2 1 TO 2
- \_3 3 TO 4
- \_4 5 to 6
- \_5 7 to 10
- \_6 More than 10

10. How often do you go to group meetings, such as associations, organizations, churches, or temples?

- \_1 NEVER
- \_2 ONCE A YEAR OR LESS
- \_3 A COUPLE OF TIMES A YEAR
- \_4 ONCE A MONTH
- \_5 2 TO 3 TIMES A MONTH
- \_6 ONCE A WEEK OR MORE

11. What is the highest educational level you have completed?

- \_1 NEVER WENT TO SCHOOL
- \_2 BETWEEN 1ST AND 5TH GRADE
- \_3 BETWEEN 6TH AND 8TH GRADE
- \_4 SOME HIGH SCHOOL
- \_5 HIGH SCHOOL GRADUATE OR "GED"
- \_6 SOME COLLEGE OR TECHNICAL SCHOOL
- \_7 COLLEGE GRADUATE
- \_8 GRADUATE DEGREE

12. Which of the following best describes your current employment status?

- ☐\_1 WORKING FULL-TIME ( $\geq 35$  HR)
- ☐\_2 PART-TIME ( $<35$  HR)
- ☐\_3 UNEMPLOYED
- ☐\_4 DISABLED
- ☐\_5 RETIRED
- ☐\_6 [Don't read] OTHER \_\_\_\_\_

13. Which of the following categories best describes your total annual household income?

- ☐\_1 LESS THAN \$5,000 PER YEAR
- ☐\_2 BETWEEN \$5,001 AND \$10,000 PER YEAR
- ☐\_3 BETWEEN \$10,001 AND \$20,000 PER YEAR
- ☐\_4 BETWEEN \$20,001 AND \$30,000 PER YEAR
- ☐\_5 MORE THAN \$30,000 PER YEAR
- ☐\_8 [Don't read] REFUSED
- ☐\_9 [Don't read] DON'T KNOW

## Section 2: HEALTH STATUS

### Health Status

1. In general, would you say your health is:

- ☐\_5 POOR
- ☐\_4 FAIR
- ☐\_3 GOOD
- ☐\_2 VERY GOOD
- ☐\_1 EXCELLENT

2. Does your health now make it hard for you to do your everyday activities? Things like moving a table, pushing a vacuum cleaner, and gardening?

- ☐\_1 YES, IT MAKES IT VERY HARD
- ☐\_2 YES, IT MAKES IT A LITTLE HARD
- ☐\_0 NO, IT DOES NOT MAKE IT HARD

3. Does your health now make it hard for you to climb several flights of stairs?

- ☐\_1 YES, IT MAKES IT VERY HARD
- ☐\_2 YES, IT MAKES IT A LITTLE HARD
- ☐\_0 NO, IT DOES NOT MAKE IT HARD

The following two questions ask about your physical health and your daily activities.

4. In the last 30 days, have you accomplished less than what you would like as a result of your physical health?

- ☐\_1 YES, YOU HAVE ACCOMPLISHED LESS
- ☐\_0 NO, YOU HAVE ACCOMPLISHED THE SAME AS USUAL

9[Don't read] DON'T KNOW

5. In the last 30 days, were you limited in the kind of work or other regular daily activities you could do as a result of your physical health?

1 YES

0 NO

9[Don't read] DON'T KNOW

The following two questions ask about your emotions and your daily activities.

6. In the last 30 days, have you accomplished less than what you would like as a result of any emotional problems, such as feeling depressed or anxious?

1 YES

0 NO

9[Don't read] DON'T KNOW

7. In the last 30 days, did you not do work or other regular daily activities as carefully as usual as a result of any emotional problems, such as feeling depressed or nervous?

1 YES, YOU DID NOT DO WORK AS CAREFULLY AS USUAL

0 NO, YOU DID DO WORK AS CAREFULLY AS USUAL

9[Don't read] DON'T KNOW

8. In the last 30 days, how much did pain interfere with your normal work (including both work outside the home and housework)?

1 NOT AT ALL

2 A LITTLE BIT

3 MODERATELY

4 QUITE A BIT

5 EXTREMELY

9. In the last 30 days, how often have you felt calm and peaceful?

1 ALWAYS

2 ALMOST ALWAYS

3 OFTEN

4 SOMETIMES

5 ALMOST NEVER

6 NEVER

10. In the last 30 days, how often did you have a lot of energy?

1 ALWAYS

2 ALMOST ALWAYS

3 OFTEN

4 SOMETIMES

5 ALMOST NEVER

6 NEVER

11. In the last 30 days, how often have you been bothered by feeling down, depressed, or hopeless?

- \_1 ALWAYS
- \_2 ALMOST ALWAYS
- \_3 OFTEN
- \_4 SOMETIMES
- \_5 ALMOST NEVER
- \_6 NEVER

12. In the last 30 days, how often have your physical or emotional problems interfered with your social activities, like visiting with friends and relatives?

- \_1 ALWAYS
- \_2 ALMOST ALWAYS
- \_3 OFTEN
- \_4 SOMETIMES
- \_5 ALMOST NEVER
- \_6 NEVER

These next two questions are about your diabetes.

13. In the last 12 months, how often has your diabetes kept you from doing your normal daily activities, such as going to work, grocery shopping, and taking care of yourself and others?

- \_1 ALWAYS
- \_2 ALMOST ALWAYS
- \_3 OFTEN
- \_4 SOMETIMES
- \_5 ALMOST NEVER
- \_6 NEVER

14. In the last 12 months, how often has your diabetes kept you from doing the kinds of things you enjoy most or wish you could do?

- \_1 ALWAYS
- \_2 ALMOST ALWAYS
- \_3 OFTEN
- \_4 SOMETIMES
- \_5 ALMOST NEVER
- \_6 NEVER

15. In the last 30 days, how many days did your health keep you in bed all or most of the day?

\_\_\_\_\_ DAYS

16. In the last 30 days, how many days did you cut down on your activities because of your health?

\_\_\_\_\_ DAYS

### Section 3: PHQ-9

Name \_\_\_\_\_ Date \_\_\_\_\_

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

(For office coding: Total Score \_\_\_\_ = \_\_\_\_ + \_\_\_\_ + \_\_\_\_)

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all    Somewhat difficult    Very difficult    Extremely difficult

☐                      ☐                      ☐                      ☐

### Section 4: PACIC

Staying healthy can be difficult when you have diabetes. We would like to learn about the type of help you get from your diabetes health care team. This team includes doctors, nurses, nutritionists, dieticians, pharmacists, diabetes educators, and telephone nurses. Remember, your answers will not be shared with anyone.

In the last 12 months, when you received care for your diabetes how often did members of your diabetes team . . .

	NEVER	RARELY	SOMETIMES	MOST OF THE TIME	ALWAYS
1. ask you for your ideas about your diabetes treatment plan?	_1	_2	_3	_4	_5

	NEVER	RARELY	SOMETIMES	MOST OF THE TIME	ALWAYS
2. give you options about your treatment to think about?	_1	_2	_3	_4	_5
3. ask to talk about any problems you had with your medications and/or their side effects?	_1	_2	_3	_4	_5
4. give you a written list of things you should do to improve your health?	_1	_2	_3	_4	_5
5. show you how taking care of your diabetes helped you?	_1	_2	_3	_4	_5
6. ask you to talk about your personal goals in caring for your diabetes?	_1	_2	_3	_4	_5
7. help you set specific goals to improve your eating habits and/or exercise?	_1	_2	_3	_4	_5
8. give you a copy of your treatment plan?	_1	_2	_3	_4	_5
9. encourage you to go to a specific group or class to help you cope with your diabetes?	_1	_2	_3	_4	_5
10. ask you questions, about your health habits, such as smoking or your exercise?	_1	_2	_3	_4	_5
11. help you make a treatment plan that you could do in your daily life?	_1	_2	_3	_4	_5

In the last 12 months when you received care for your diabetes, how often did your diabetes team...

	NEVER	RARELY	SOMETIMES	MOST OF THE TIME	ALWAYS
12. help you plan ahead so you could take care of your diabetes even in hard times?	_1	_2	_3	_4	_5
13. ask you about how your diabetes affects your life?	_1	_2	_3	_4	_5
14. contact you after a visit or between visits to see how things were going?	_1	_2	_3	_4	_5

	NEVER	RARELY	SOMETIMES	MOST OF THE TIME	ALWAYS
15. encourage you to attend programs in the community that could help you with your diabetes?	_1	_2	_3	_4	_5
16. refer you to a nutritionist, a health educator, or counselor?	_1	_2	_3	_4	_5
17. tell you how your visits with other type of doctors, like the eye doctor or surgeon, could help your diabetes treatment?	_1	_2	_3	_4	_5
18. ask you how visits with other doctors were going?	_1	_2	_3	_4	_5
19. [Don't Read Stem] how often did you feel that your treatment plan was well organized?	_1	_2	_3	_4	_5
20. think about your values and cultural traditions when they recommended a treatment?	_1	_2	_3	_4	_5

## Section 5: QHELP, QLEARN, & QFORM

We'd like to ask you some questions about your experience with written or printed information that you might get in this clinic. Please try to answer them the best you can.

1. How often do you have someone like a family member, friend, hospital or clinic worker or caregiver, help you read hospital materials?

\_5 ALWAYS  
 \_4 OFTEN  
 \_3 SOMETIMES  
 \_2 RARELY  
 \_1 NEVER

2. How often do you have problems learning about your medical condition because of difficulty understanding written information?

\_5 ALWAYS  
 \_4 OFTEN

\_3SOMETIMES  
 \_2RARELY  
 \_1NEVER

3. How confident are you filling out forms by yourself?

\_5EXTREMELY  
 \_4QUITE A BIT  
 \_3SOMEWHAT  
 \_2A LITTLE  
 \_1NOT AT ALL

## Section 6: IPC & LANGUAGE ACCESS BARRIERS

The next questions are about your experiences talking with your diabetes health care team. Your diabetes health care team could include doctors, nurses, nutritionists, dieticians, pharmacists, diabetes educators, and telephone nurses. When answering these questions, please think about your overall experience with all the members of your diabetes health care team, not just your doctor. Remember, your answers will not be shared with anyone at the clinic.

In the last 12 months, how often did members of your diabetes team . . .

	ALWAYS	OFTEN	SOME- TIMES	RARELY	NEVER	DON'T KNOW
1. give you enough time to say what you thought was important?	_1	_2	_3	_4	_5	_9
2. listen carefully to what you had to say?	_1	_2	_3	_4	_5	_9
3. give you enough information about your health problems?	_1	_2	_3	_4	_5	_9
4. make sure you understood your health problems?	_1	_2	_3	_4	_5	_9
5. give you results of a test <u>without</u> enough of an explanation?	_1	_2	_3	_4	_5	_9
6. give you written health information in [Language you are most comfortable speaking] such as pamphlets, about your health problems?	_1	_2	_3	_4	_5	_9
7. tell you what to do if your health problem did not improve?	_1	_2	_3	_4	_5	_9
8. tell you what you could do to take care of yourself at home?	_1	_2	_3	_4	_5	_9

	ALWAYS	OFTEN	SOME-TIMES	RARELY	NEVER	DON'T KNOW
9. make you feel confused about what was going on with your medical care because they did not explain things well?	_1	_2	_3	_4	_5	_9

In the last 12 months, how often did members of your diabetes team . . .

	ALWAYS	OFTEN	SOME-TIMES	RARELY	NEVER	DON'T KNOW
10. tell you how to pay attention to your symptoms and when to call them?	_1	_2	_3	_4	_5	_9
11. explain clearly to you <u>how</u> to take your medicine?	_1	_2	_3	_4	_5	_9
12. go over <u>all</u> of the medicines you were taking?	_1	_2	_3	_4	_5	_9
13. give you <u>written</u> instructions, [in the language you are most comfortable speaking] about how to take your medicine, other than what was on the container?	_1	_2	_3	_4	_5	_9
14. give you pictures or calendars to help explain how to take the medicine?	_1	_2	_3	_4	_5	_9
15. tell you the reasons for taking your medicines?	_1	_2	_3	_4	_5	_9
16. tell you about side-effects you might get from your medicine?	_1	_2	_3	_4	_5	_9
17. make you feel that following your treatment plan would make a difference in your health?	_1	_2	_3	_4	_5	_9
18. make you feel that your everyday activities such as your diet and lifestyle would make a difference in your health?	_1	_2	_3	_4	_5	_9
19. ask if you might have any problems actually <u>doing</u> the recommended treatment?	_1	_2	_3	_4	_5	_9

	ALWAYS	OFTEN	SOME-TIMES	RARELY	NEVER	DON'T KNOW
20. understand the kinds of problems you might have in doing the recommended treatment?	_1	_2	_3	_4	_5	_9

In the last 12 months, how often did members of your diabetes team . . .

	ALWAYS	OFTEN	SOME-TIMES	RARELY	NEVER	DON'T KNOW
21. use medical words that you did not understand?	_1	_2	_3	_4	_5	_9
22. [DON'T READ STEM] how often did you have trouble understanding members of your diabetes team because they spoke too fast?	_1	_2	_3	_4	_5	_9

[If PATIENT FEELS MOST COMFORTABLE SPEAKING ENGLISH, SKIP TO ITEM 5]

In the last 12 months . . .

	NEVER	RARELY	SOME-TIMES	OFTEN	ALWAYS	DON'T KNOW
1. How often did you need an interpreter, including family members, when you saw members of your diabetes team?	_1	_2	_3	_4	_5	_9
2. Not including interpreters, how often did the members of your diabetes team speak [Language most comfortable speaking] with you?	_1	_2	_3	_4	_5	_9
3. did you have problems understanding or communicating with members of your diabetes team because he/she did not speak [Language most comfortable speaking]?	_1	_2	_3	_4	_5	_9
4. How often did you have problems with your diabetes care because you had to wait for an interpreter?	_1	_2	_3	_4	_5	_9

## Section 7: SELF-CARE

Despite their best efforts, many patients find it hard to follow all the recommendations about their diabetes. Most patients are recommended to lose weight, exercise, take medications, or quit smoking, but often find it difficult to do so. Please answer the following questions as honestly as possible.

In the last 12 months, how difficult has it been for you doing the following exactly as members of your diabetes team recommended?

1. Taking diabetes medications, such as pills or insulin?

- ☐ 1 SO DIFFICULT THAT YOU COULDN'T DO IT AT ALL
- ☐ 2 VERY DIFFICULT, YOU HARDLY EVER DO IT
- ☐ 3 DIFFICULT, BUT YOU COULD DO IT SOME OF THE TIME
- ☐ 4 NOT DIFFICULT, YOU COULD DO IT MOST OF THE TIME
- ☐ 5 NOT DIFFICULT, YOU GOT IT EXACTLY RIGHT
- ☐ 6 [Don't read] DOESN'T APPLY, YOU DON'T DO IT, OR MEMBERS OF YOUR DIABETES TEAM DID NOT RECOMMEND IT

2. Exercising regularly?

- ☐ 1 SO DIFFICULT THAT YOU COULDN'T DO IT AT ALL
- ☐ 2 VERY DIFFICULT, YOU HARDLY EVER DO IT
- ☐ 3 DIFFICULT, BUT YOU COULD DO IT SOME OF THE TIME
- ☐ 4 NOT DIFFICULT, YOU COULD DO IT MOST OF THE TIME
- ☐ 5 NOT DIFFICULT, YOU GOT IT EXACTLY RIGHT
- ☐ 6 [Don't read] DOESN'T APPLY, YOU DON'T DO IT, OR MEMBERS OF YOUR DIABETES TEAM DID NOT RECOMMEND IT

3. Following your recommended eating plan?

- ☐ 1 SO DIFFICULT THAT YOU COULDN'T DO IT AT ALL
- ☐ 2 VERY DIFFICULT, YOU HARDLY EVER DO IT
- ☐ 3 DIFFICULT, BUT YOU COULD DO IT SOME OF THE TIME
- ☐ 4 NOT DIFFICULT, YOU COULD DO IT MOST OF THE TIME
- ☐ 5 NOT DIFFICULT, YOU GOT IT EXACTLY RIGHT
- ☐ 6 [Don't read] DOESN'T APPLY, YOU DON'T DO IT, OR MEMBERS OF YOUR DIABETES TEAM DID NOT RECOMMEND IT

4. Checking your blood sugar by pricking your finger?

- ☐ 1 SO DIFFICULT THAT YOU COULDN'T DO IT AT ALL
- ☐ 2 VERY DIFFICULT, YOU HARDLY EVER DO IT
- ☐ 3 DIFFICULT, BUT YOU COULD DO IT SOME OF THE TIME
- ☐ 4 NOT DIFFICULT, YOU COULD DO IT MOST OF THE TIME
- ☐ 5 NOT DIFFICULT, YOU GOT IT EXACTLY RIGHT
- ☐ 6 [Don't read] DOESN'T APPLY, YOU DON'T DO IT, OR MEMBERS OF YOUR DIABETES TEAM DID NOT RECOMMEND IT

5. Checking your feet for wounds and sores?

- ☐ 1 SO DIFFICULT THAT YOU COULDN'T DO IT AT ALL  
☐ 2 VERY DIFFICULT, YOU HARDLY EVER DO IT  
☐ 3 DIFFICULT, BUT YOU COULD DO IT SOME OF THE TIME  
☐ 4 NOT DIFFICULT, YOU COULD DO IT MOST OF THE TIME  
☐ 5 NOT DIFFICULT, YOU GOT IT EXACTLY RIGHT  
☐ 6 [Don't read] DOESN'T APPLY, YOU DON'T DO IT, OR MEMBERS OF YOUR DIABETES TEAM DID NOT RECOMMEND IT

Section 8: Diet

The next few questions are about the foods you eat.

6. In the last 7 days, how many days did you follow a healthy eating plan?

\_0 0      \_1 1      \_2 2      \_3 3      \_4 4      \_5 5      \_6 6      \_7 7

7. In the last 30 days, how many days per week did you follow a healthy eating plan?

\_0 0      \_1 1      \_2 2      \_3 3      \_4 4      \_5 5      \_6 6      \_7 7

8. In the last 7 days, how many days did you eat 5 or more fruits or vegetables per day?

Remember, this could be five fruits, or five vegetables or a mixture, such as two fruits and three vegetables.

\_0 0      \_1 1      \_2 2      \_3 3      \_4 4      \_5 5      \_6 6      \_7 7

9. In the last 7 days, how many days did you eat high fat foods, such as red meat, butter, ice cream, deep fried food, lard, mayonnaise or fried rice?

\_0 0      \_1 1      \_2 2      \_3 3      \_4 4      \_5 5      \_6 6      \_7 7

10. In the last 7 days, how many days did you spread evenly throughout the day starchy foods, such as bread, tortillas, or rice?

\_0 0      \_1 1      \_2 2      \_3 3      \_4 4      \_5 5      \_6 6      \_7 7

Exercise

The next few questions are about exercise.

11. In the last 7 days, how many days did you do at least 30 minutes of physical activity? Like walking or gardening. [IF 0 DAYS, SKIP TO ITEM 12]

\_0 0      \_1 1      \_2 2      \_3 3      \_4 4      \_5 5      \_6 6      \_7 7

11(a). And how many total minutes or hours did you do physical activity for the week?

\_\_\_\_\_ \_1 HOURS / \_2 MINUTES

12. In the last 7 days, how many days did you do 30 minutes or more of the kind of exercise that makes you breathe hard, such as swimming, walking fast, or biking? [IF 0 DAYS, SKIP TO ITEM 13]

\_0 0      \_1 1      \_2 2      \_3 3      \_4 4      \_5 5      \_6 6      \_7 7

12(a). And how many total minutes or hours did you do exercise for the week?

\_\_\_\_\_ \_1 HOURS / \_2 MINUTES

#### Blood sugar testing

The next few questions are about checking your blood sugar. We know that checking your blood sugar can sometimes be difficult.

13. In the last 7 days, how many days did you test your blood sugar?

\_0 0      \_1 1      \_2 2      \_3 3      \_4 4      \_5 5      \_6 6      \_7 7

14. In the last 7 days, how many days did you test your blood sugar the number of times recommended by your doctor or nurse?

\_0 0      \_1 1      \_2 2      \_3 3      \_4 4      \_5 5      \_6 6      \_7 7

#### Foot Care

The next few questions are about your feet.

15. In the last 7 days, how many days did you carefully check your feet for cuts, sores or other problems?

\_0 0      \_1 1      \_2 2      \_3 3      \_4 4      \_5 5      \_6 6      \_7 7

16. In the last 7 days, how many days did you check the inside of your shoes, looking for pebbles or sharp

objects?

\_0 0      \_1 1      \_2 2      \_3 3      \_4 4      \_5 5      \_6 6      \_7 7

17. In the last 7 days, how many days did you wash your feet with soap and water?

\_0 0      \_1 1      \_2 2      \_3 3      \_4 4      \_5 5      \_6 6      \_7 7

18. In the last 7 days, how many days did you soak your feet?

\_0 0      \_1 1      \_2 2      \_3 3      \_4 4      \_5 5      \_6 6      \_7 7

19. In the last 7 days, how many days did you use a towel to dry between your toes after washing?

\_0 0      \_1 1      \_2 2      \_3 3      \_4 4      \_5 5      \_6 6      \_7 7

#### Smoking

20. In the last 6 months, did any member of your diabetes team ask you whether or not you smoke cigarettes?

\_1 YES  
\_0 NO

21. Have you smoked a cigarette in the last 6 months --- even one puff?

\_1 YES  
\_0 NO [IF NO, SKIP TO ITEM 26]

22. In the last 6 months, did any member of your diabetes team recommend you stop smoking, offer to refer you to a stop-smoking program, or support you to quit in any way?

\_1 YES  
\_0 NO

23. Have you quit or tried to quit smoking in the last 6 months?

\_1 YES, YOU QUIT SMOKING  
\_2 YES, YOU TRIED TO QUIT BUT DID NOT SUCCEED  
\_0 NO, YOU DID NOT TRY TO QUIT SMOKING

24. In the last 7 days, have you smoked a cigarette --- even one puff?

\_1 YES  
\_0 NO [IF NO, SKIP TO ITEM 26]

25. In the last 7 days, how many cigarettes did you smoke on a typical day?

\_\_\_\_\_ CIGARETTES

## Medications

Now I will ask you some questions about your medications. Many people miss taking their medication sometimes, so it's okay if you tell me you don't always take all of your medications.

26. Have you been prescribed or told by a member of your diabetes team to take insulin?

- ☐ 1 YES  
☐ 0 NO [IF NO, SKIP TO ITEM 28]  
☐ 9 [Don't read] DON'T KNOW [IF DON'T KNOW, SKIP TO ITEM 28]

27. In the last 7 days, how many days did you MISS even one insulin shot?  
[Read options]

- ☐ 00 DAYS  
☐ 11 DAY  
☐ 22 DAYS  
☐ 33 DAYS  
☐ 44 DAYS  
☐ 55 DAYS  
☐ 66 DAYS  
☐ 77 DAYS

28. Have you been prescribed or told by a member of your diabetes team to take diabetes pills?

- ☐ 1 YES  
☐ 0 NO  
☐ 9 [Don't read] DON'T KNOW } [IF NO OR DON'T KNOW, SKIP TO ITEM 30]

29. In the last 7 days, how many days did you MISS even one diabetes pill?  
[Read options]

- ☐ 00 DAYS  
☐ 11 DAY  
☐ 22 DAYS  
☐ 33 DAYS  
☐ 44 DAYS  
☐ 55 DAYS  
☐ 66 DAYS  
☐ 77 DAYS

30. Have you been prescribed or told by a member of your diabetes team to take blood pressure pills?

- ☐ 1 YES  
☐ 0 NO  
☐ 9 [Don't read] DON'T KNOW } [IF NO OR DON'T KNOW, SKIP TO ITEM 32]

31. In the last 7 days, how many days did you MISS even one blood pressure pill? [Read options]

- ☐ 00 DAYS  
☐ 11 DAY  
☐ 22 DAYS

33 DAYS  
 44 DAYS  
 55 DAYS  
 66 DAYS  
 77 DAYS

32. Have you been prescribed or told by a member of your diabetes team to take pills to lower your cholesterol?

1 YES  
 0 NO  
 9 [Don't read] DON'T KNOW

\_\_\_\_\_ } **[If NO OR DON'T KNOW, SKIP TO ITEM 34]**

33. In the last 7 days, how many days did you MISS even one cholesterol pill?  
[Read options]

00 DAYS  
 11 DAY  
 22 DAYS  
 33 DAYS  
 44 DAYS  
 55 DAYS  
 66 DAYS  
 77 DAYS

34. Have you been prescribed or told by a member of your diabetes team to take aspirin?

1 YES  
 0 NO  
 9 [Don't read] DON'T KNOW

\_\_\_\_\_ } **[If NO OR DON'T KNOW, SKIP TO SECTION 10]**

35. In the last 7 days, how many days did you MISS even one aspirin pill?  
[Read options]

00 DAYS  
 11 DAY  
 22 DAYS  
 33 DAYS  
 44 DAYS  
 55 DAYS  
 66 DAYS  
 77 DAYS

### Section 8: ACPF PAM Interview

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. Your answers should be what is true for you and not just what you think the doctor wants you to say. If the statement does not apply to you, circle N/A.

When all is said and done, I am the person who is responsible for managing my health condition(s).	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
--	-------------------	----------	-------	----------------	-----

Taking an active role in my own health care is the most important factor in determining my health and ability to function.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health condition(s).	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I know what each of my prescribed medications does.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident that I can tell when I need to go get medical care and when I can handle a health problem myself.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident I can tell a doctor concerns I have even when he or she does not ask.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident that I can follow through on medical treatments I need to do at home.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I understand the nature and causes of my health condition(s).	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I know the different medical treatment options available for my health condition(s).	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I have been able to maintain the lifestyle changes for my health condition(s) that I have made.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I know how to prevent further problems with my health condition(s).	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident I can figure out solutions when new situations or problems arise with my health condition(s).	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident that I can maintain lifestyle changes, like diet and exercise, even during times of stress.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

## Section 9: QUALITY OF DIABETES CARE

- Thinking about the last 12 months, how would you rate the quality of care you received for your diabetes? Use a number from 0 to 10, where 0 is the worst diabetes care possible and 10 is the best diabetes care possible.

\_\_\_\_\_ [enter number]

2. How much would you recommend your diabetes team to your family or friends if they needed diabetes care?

- ☐ 1 YOU WOULD NOT RECOMMEND IT
- ☐ 2 YOU WOULD RECOMMEND IT JUST A LITTLE
- ☐ 3 YOU WOULD RECOMMEND IT A MODERATE AMOUNT
- ☐ 4 YOU WOULD STRONGLY RECOMMEND IT

The next four statements are about the diabetes care you have received in the last 12 months. Please tell me how much you agree or disagree with the following statements.

3. You are very satisfied with the diabetes care you received.

- ☐ 1 STRONGLY DISAGREE
- ☐ 2 DISAGREE
- ☐ 3 NEITHER DISAGREE NOR AGREE
- ☐ 4 AGREE
- ☐ 5 STRONGLY AGREE

4. Most people receive diabetes care that is probably better than what you received.

- ☐ 1 STRONGLY DISAGREE
- ☐ 2 DISAGREE
- ☐ 3 NEITHER DISAGREE NOR AGREE
- ☐ 4 AGREE
- ☐ 5 STRONGLY AGREE

5. The diabetes care you received in the last 12 months is just about perfect.

- ☐ 1 STRONGLY DISAGREE
- ☐ 2 DISAGREE
- ☐ 3 NEITHER DISAGREE NOR AGREE
- ☐ 4 AGREE
- ☐ 5 STRONGLY AGREE

6. There are things about the diabetes care you received that could be better.

- ☐ 1 STRONGLY DISAGREE
- ☐ 2 DISAGREE
- ☐ 3 NEITHER DISAGREE NOR AGREE
- ☐ 4 AGREE
- ☐ 5 STRONGLY AGREE

7. How would you describe the diabetes care you have received in the last 12 months?

- ☐ 1 EXCELLENT
- ☐ 2 VERY GOOD
- ☐ 3 GOOD
- ☐ 4 FAIR
- ☐ 5 POOR

8. In the last 12 months, how many days did you usually have to wait between needing to get diabetes care and SEEING a member of your diabetes team?

- ☐ 1 SAME DAY

- ☐ 21 DAY
- ☐ 32 DAYS
- ☐ 43 DAYS
- ☐ 54-7 DAYS
- ☐ 68-14 DAYS
- ☐ 715 DAYS OR LONGER
- ☐ 9[Don't read] NOT APPLICABLE

9. In the last 12 months, have you been to the eye doctor, not the doctor who makes glasses, but the one who looks in the back of the eye?

- ☐ 1 YES
- ☐ 0 NO

## POST SURVEY COMMENTS

Thank you very much for doing the survey. We are finished with the interview. Do you have any questions, comments, or suggestions about the interview that you would like to share with me?

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I really enjoyed talking with you. Also, the information you have given me will be helpful in understanding more about diabetes care and the relationship you have with your health team.

### **Attachment 4:**

#### **Text from the Original AHRQ Grant regarding data and privacy protections and safeguards**

Taken from the AHRQ Grant section 5. Note that this grant was submitted jointly by the SFHP and UCSF, so that it covers both data protection concerns related to the ATSM Project and the ATSM Evaluation Study.

#### **5e. Data and Privacy Protections**

The proposed project will ensure data protection at several levels. Most protections will take place for activities occurring at the SFHP for generating patient lists and conducting the ATSM interventions. Protections will be set up for using data from the ATSM Prosodie company (for patient reports from the ATSM system), from the CHNSF data systems (for identifying patients for ATSM interventions), and from the SFHP pharmacy claims data (for identifying patients for ATSM-PLUS). A sample of approximately 260 patients will also be enrolled in the UCSF CRN research study for Specific Aims 1 and 2, and these patients will also be protected through the application of UCSF Committee on Human Research protections for human subjects (see next section).

#### **5e.1 Assurances of HIPAA Compliance within these Activities**

**Implementation of Common Framework Guidelines-** We have reviewed the health information exchange guidelines contained in the Common Framework (<http://healthit.ahrq.gov/hiepolicyissues>) and incorporated key components into this project. First, we will minimize the frequency of health information exchange (HIE) between the SFHP, CHNSF, and UCSF with most activities involving providing data to the SFHP for internal merging and development of integrated datasets to occur within SFHP. Additionally, in concordance with these guidelines we will develop Data Agreements among participants.

#### **Transfer of existing data from CHNSF and Prosodie to SFHP**

Both the CHNSF and Prosodie have HIPAA-compliant protections built into their data agreements that have been demonstrated to be effective in past Health Information Exchange activities. In the proposed study, all HIE in the form of datasets that pertain to patient clinical, pharmacy, and ATSM-related data will be transferred to and remain at SFHP. The SFHP has recommended that established protocols can easily be modified to ensure data privacy and HIPAA protections for: (1) FTP activities between the SFHP and CHNSF and Prosodie, and (2) use of Data Agreements for authorizing personnel in regard to documenting the transfer of data between different organizations (Rich Rubinstein, Senior Counsel SFHP, personal communication Jan 31, 2007). SFHP staff will contact patients about the ATSM programs and at the same time will ask the patients during the Aim 1 recruitment period if they would agree to be contacted by a UCSF research assistant.

**Patient recruitment-** Patients who agree will then be contacted by UCSF research assistants who will obtain verbal consent in cases where patients agree to the research study. At this point, UCSF research assistants will not have access to any personal medical information - they will only have patients' last name, language, and telephone number. Patients who agree to

participate in the SFHP-ATSM program but are not interested in enrolling in the UCSF CRN study will not be contacted further regarding the study.

At the end of the study period, the SFHP will create a de-identified dataset for all patients in the SFHP with diabetes over the study period. This dataset will be sent to UCSF researchers identified in the data agreement.

**Attachment 5:**  
**Waiver Form**

UCSF

**COMMITTEE ON HUMAN RESEARCH APPLICATION**

**SUPPLEMENT: REQUEST FOR WAIVER OF CONSENT/AUTHORIZATION**  
**for MINIMAL RISK RESEARCH or for SCREENING FOR RECRUITMENT**

Principal Investigator of CHR application:		
Name and degree Dean Schillinger MD	University Title Associate Clinical Professor	Department DGIM
Campus Mailing Address (Box No.) 1364	Phone Number 415-206-8940	E-mail Address dschillinger@medsfgh.ucsf.edu
CHR Approval Number:		
Study Title (may not exceed 500 characters): Harnessing Health IT for Self-Management Support and Medication Activation in a Medicaid Health Plan		

<p>Waiving informed consent for research must satisfy Federal regulations for Protection of Human Subjects, 45 CFR 46, and Standards for Privacy of Individually Identifiable Health Information (a.k.a., HIPAA), 45 CFR 164.512 [Note: There are no corresponding provisions in FDA regulations, and these criteria cannot be used to completely waive consent in FDA-regulated studies. Waiver of consent/authorization for recruitment purposes may still be allowed.]</p> <p>§ 45 CFR 46.116(d): An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:</p> <p>(1) the research involves no more than minimal risk to the subjects;</p> <p>(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;</p> <p>(3) the research could not practicably be carried out without the waiver or alteration; and</p> <p>(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.</p>
Is this waiver for screening of medical records for recruitment purposes only? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Does study participation pose minimal risk (including minimal risk to privacy) to the subjects? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Can this study be done without access to or use of Protected Health Information (PHI)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If "No," explain how PHI is protected, where it will be stored, who will have access to it, and when it will be destroyed.
For the evaluation that UCSF will be conducting for the SFHP of a behavioral intervention on clinical outcomes, UCSF

will only have de-identified data and will not be in possession of PHI at any time.
<p>Explain why it is not practicable to obtain informed consent.</p> <p>We will do verbal consent with all patients who are interested in participating in the evaluation. The patients will be contacted via telephone by the San Francisco Health Plan (SFHP) about the intervention that the SFHP is conducting, and only if they agree to be contacted about the separate evaluation will we, as UCSF researchers, receive their contact information, including name, language and phone number. We will call patients directly after they agree to be contacted and will explain the study and obtain verbal consent using a script. UCSF will protect their privacy by using phone consent and will limit the number of contacts with patients.</p>
Are subjects' rights and welfare adversely affected by waiving informed consent? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<p>Will subjects be provided with additional pertinent information after their participation? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If "Yes," describe the process and submit any post-enrollment information sheets or consent forms for review.</p> <p>We will give patients our contact information so that they can ask questions if they arise about the evaluation.</p>

<p>I assure that:</p> <ul style="list-style-type: none"> <li>▪ <u>the above information is accurate,</u></li> <li>▪ <u>all study personnel will comply with HIPAA regulations,</u></li> <li>▪ <u>the protected health information requested is the minimum necessary to meet the research objectives, and that</u></li> <li>▪ <u>the protected health information I obtain as part of this research will not be reused or disclosed to any other person other than the study personnel, except as required by law.</u></li> </ul>          <div style="display: flex; justify-content: space-between;"> <div style="width: 45%; border-top: 1px solid black; text-align: center;">Principal Investigator's Signature</div> <div style="width: 45%; border-top: 1px solid black; text-align: center;">Date</div> </div>
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